



Applicants: Gotwals, et al.  
Application No.: 09/423,018  
Filed: October 12, 2000  
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Docket No. A018 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Gotwals, et al.  
Application No.: 09/423,018                      Group Art Unit: 1646  
Filed: October 12, 2000                      Examiner: Janet L. Andres Ph.D.  
Title: TYPE II TGF-BETA RECEPTOR/IMMUNOGLOBULIN CONSTANT  
REGION FUSION PROTEINS

Mail Stop Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

SUPPLEMENTARY DECLARATION OF RICHARD CATE, Ph. D


I, Richard Cate, being duly sworn, depose and state as follows.

1. I am an Applicant named in the above-identified patent application. I have reviewed and am familiar with the contents of the April 20, 2004 Office Action issued in connection with the patent application. On October 15, 2004, I submitted a declaration in support of the patentability of the pending claims in the instant application ("October 15, 2004 Declaration").
2. In paragraph four of the October 15, 2004 Declaration, I represented that, to the best of my knowledge, prior to April 18, 1997, there were no known fusion proteins comprising mammalian type II receptors of the TGF- $\beta$  receptor family and a constant region of an immunoglobulin besides the TGF- $\beta$  RII fusion protein produced by the Applicants in connection with the making of the claimed invention.
3. After the October 15, 2004 Declaration was filed, I reviewed *Isaka, Journal of the American Society of Nephrology, 1996, 7(9), p. 1735, Abstract A2411, XP008024430* ("*Isaka*"), which was cited in the EPO counterpart of the instant application. *Isaka* was also cited in the April 5, 2004 IDS filed in the instant application.
4. *Isaka* tested whether a soluble TGF- $\beta$  RII -IgG inhibited TGF- $\beta$  *in vitro*, and whether a nucleotide sequence encoding TGF- $\beta$  RII -IgG could be used

*in vivo* to inhibit fibronectin generation in the rat kidney.

5. Accordingly, I hereby correct the aforementioned representation in paragraph 4 of the October 15, 2004 Declaration and note that *Isaka* published a fusion protein comprising a mammalian type II receptor of the TGF- $\beta$  receptor family and a constant region of an immunoglobulin prior to April 18, 1997. I otherwise maintain that the pending claims are patentable over the prior art (including *Isaka*) for the reasons of record.

6. I understand that willful false statements and the like made in connection with this declaration are punishable by fine or imprisonment, or both (18 U.S.C. §1001).

  
Richard Cate, Ph. D.

December 1, 2004